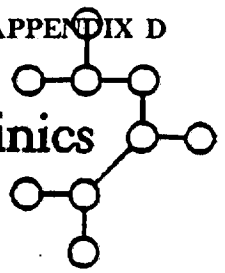
GHBA/Hazleton Clinics
Leeds



INDEPENDENT REVIEW BOARD

CONSTITUTION

1. Name and Purpose

1.1 The Board shall be called the "Independent Review Board".

1.2 The responsibility of the IRB shall be:

- to protect the safety, rights and dignity of human subjects involved in clinical research studies
- to ensure the science warrants exposure of subjects to risk
- to ensure that applicable laws, regulations and standard operating procedures are followed.

2. Membership

2.1 The Board shall consist of twenty members.

2.2 The Board must include at least one woman and one man.

2.3 At least one member must be a registered medical practitioner.

2.4 At least one member must represent a non-scientific field.

2.5 A quorum consists of five members and must include a registered medical practitioner, a non-medical scientist and a non-scientist, both sexes should be represented.

2.6 Members shall serve for one year terms from 1 August. Consecutive terms of service are encouraged to provide continuity to the Board's activities.

2.7 It is the responsibility of the Managing Director of GHBA/Hazleton Clinic Leeds to nominate members of the IRB. The Chairman is appointed by the Managing Director of GHBA/Hazleton Clinic Leeds for a one year term which may be renewed at the MD's discretion.

3. Authority

3.1 The IRB has the sole power to approve, modify or disapprove all study protocols and informed consents for studies involving human subjects.

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3.2 Requirements for modification or disapproval of either a protocol or an informed consent may not be over-ruled by any number of GHBA/Hazleton's staff.

4. Meetings

Meetings are scheduled for the first and third Tuesday of every month at 6.30 p.m. Meetings are held at GHBA/Hazleton Clinic Leeds. If a meeting is not required, the Medical Director will inform the Chairman so Board members can be notified of the cancellation.

5. Voting

5.1 Voting will be oral upon a call of roll of the members present.

5.2 The decision of the IRB to approve or disapprove will be that expressed by a majority of the members present with all votes carrying equal weight. In the case of approval, at least one of the affirmative votes must be cast by a physician.

6. Reporting Results of Review

Results of an IRB review are submitted to the Principal Investigator on a pro forma, signed by the Chairman, or his alternate. This form will also include any requirements for amendment or modification to the protocol or informed consent.

7. Records

The IRB will be required to maintain:

7.1 Copies of all research proposal documentation submitted for review, together with completion notices detailing any adverse events.

7.2 Minutes of meetings to contain the names of members and others in attendance, decisions of the Board and the basis for disapproval of any proposal. Individual votes will be recorded.

7.3 A file containing name and qualifications of each member of the Board and their representative capacity.

7.4 A set of Standard Operating Procedures (both current and historical) which shall be circulated to each member and alternate at least once every twelve months.

8. Finance

8.1 Members shall receive travelling expenses for attendance at meetings.

8.2 GHBA/Hazleton will pay the sum of £15 per protocol reviewed either to each member or to a charity of their choice.

This Constitution is a resume of the Standard Operating Procedures by which the function of the IRB is regulated.

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